

Amendment and Response

Applicant: Jeffrey W. Chambers

Serial No.: 10/812,250

Filed: March 29, 2004

Docket No.: C364.105.101

Title: STENT POSITIONING SYSTEM AND METHOD

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed February 12, 2008. In that Office Action, claims 28-30, 32, and 34-41 were rejected under 35 U.S.C. §103(a) as being unpatentable over Saltiel, U.S. Patent No. 6,458,151 ("Saltiel") in view of Zikorus et al., U.S. Publication No. 2002/0068866. Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Saltiel in view of Zikorus as applied to claim 30 above, and further in view of Close et al., U.S. Patent No. 6,532,380 ("Close"). Claim 33 was rejected under 35 U.S.C. §103(a) as being unpatentable over Saltiel in view of Zikorus as applied to claim 28 above, and further in view of Shaknovich, U.S. Patent No. 5,749,890 ("Shaknovich").

With this Response, claims 42-45 have been added. Claims 28-45 remain pending in the application and are presented for consideration and allowance.

35 U.S.C. §103 Rejections

In rejecting claim 28, the Office Action concedes that Saltiel fails to disclose deploying a deployment site locator having a plurality of rods. In fact, Saltiel describes an expandable member 20 comprised of a singular, longitudinally rigid body 22. To address this deficiency, the Office Action references Zikorus, and asserts that the expandable electrode device 56 is a "deployment site locator," and that the plurality of electrodes 58 are "rods". Based on this interpretation, the Office Action asserts that one of skill would have considered it obvious to modify the longitudinally rigid body 22 of Saltiel to incorporate the expandable electrode device 56 of Zikorus to detect an ostium with the method of Saltiel to deliver a stent to a location adjacent the ostium. Applicant respectfully disagrees.

For example, Zikorus does not teach that the expandable electrode device 56, and in particular the expandable electrodes 58 carried thereby, determine a position of an ostium (or other structure), let alone with the electrodes 58 in an expanded state as otherwise set forth in claim 28. Paragraph 26 of Zikorus Describes the methodology by which a SFJ is "detected," via an electrode device 32. In this regard, Paragraph 26 clarifies that the expandable electrode device is transitioned to the expanded state only after the SFJ has been detected. Thus, Zikorus

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cannot be viewed as informing one of skill of a technique in which deployed “rods” are used to determine a position of an ostium. In fact, the only contacting-type procedure relating to an ostium as disclosed in Zikorus is described at Paragraph 47 with respect to a hook-shaped tip 117 as shown in FIG. 8. The hook 117 is clearly not part of the radially deployed electrodes 104, and thus is not part of the alleged “plurality of rods” of Zikorus as identified in the Office Action. In summary, nothing in Zikorus teaches “an alternative site detection means that expands having rods” as asserted in the Office Action. In light of this failure, it is respectfully requested that the rejection of claim 28 be withdrawn.

In addition to the above, modifying Saltiel to incorporate the expanding array of electrodes 58 of Zikorus would improperly render Saltiel inoperable and/or unfit for its intended purpose. Under these circumstances, an obviousness rejection cannot be maintained. *MPEP* §2143.01. Zikorus describes that the electrodes 58 are carried by primary leads, with the primary leads “moving” an indeterminate distance, limited only by contact of the primary electrodes 58 with a vein wall. *Zikorus at Para. 29*. Upon application of RF energy, the electrodes are pressed closer together by the shrinking vein wall to assume a reduced profile shape. *Zikorus at Para. 30*. Clearly, then, the electrodes/leads 58 are highly flexible, and do not exhibit longitudinal rigidity. In contrast, Saltiel requires that the expandable member body 22 be longitudinally rigid such that an overall length of the stent positioning device 10 does not change when the distal end 24 thereof contacts an ostium. *Saltiel at col. 3, ll. 32-40*. In fact, Saltiel relies upon this longitudinal rigidity to affirmatively establish the predetermined distance or length L_1 between the distal end 24 of the expandable member 20 relative to a proximal end of the manifold 14 in order to ensure accurate positioning of the stent 100 relative to the distal end 24. Thus, were the longitudinally rigid body 22 replaced with the flexible electrodes/leads 58 of Zikorus, this necessary, longitudinally stable length would no longer exist, such that the known relationship between the stent 100 and the expandable member 20 would no longer be available. As a result, the Saltiel device (and related methods of use) could not function as intended.

For at least the above reasons, it is respectfully submitted that claim 28 is allowable over the cited art. Claims 29-41 depend from claim 28, and thus are also allowable.

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Newly Presented Claims

Newly presented claim 42 depends from claim 28 and thus, for at least the above reasons, is allowable. In addition, claim 42 recites that the step of extending the plurality of rods occurs prior to placement of the stent within the vessel to be stented. Support for this language is found, for example in FIGS. 19A-19E. In contrast, the methods of Saltiel require that the stent 100 is first positioned or placed within a vessel (i.e., distal the ostium), followed by deployment of the expandable member 20. Following engagement of the ostium with the expandable member 20, the stent 100 is then retracted in the proximal direction relative to the vessel. *Saltiel at col. 5, l. 55 – col. 6, l. 21*. Thus, it is respectfully submitted that claim 42 recites additionally allowable subject matter.

Newly presented claim 43 depends from claim 28 and thus, for at least the above reasons, is allowable. In addition, claim 43 recites that each of the rods extends from the base to a free end opposite the base to define an intermediate segment therebetween. Further, claim 43 provides that the step of contacting bodily structures immediately proximate the ostium includes the intermediate segment of at least one of the rods contacting the bodily structure. Support for this language is found, for example, at FIG. 19B. In contrast, Saltiel is limited to, and relies upon, engagement of the ostium only by the distal end 24 of the expandable member 20. *Saltiel at col. 6, ll. 12-16*. With the longitudinally rigid expandable member 22 having a known, unchanging distance between the distal end 24 and the manifold 14, the stent 100 can then be positioned by the stent catheter 50 via placement of the proximal visible marker 60. *Saltiel at col. 6, ll. 16-24*. The inventive method of claim 43 is less traumatic to the engaged tissue, with the engagement force(s) being distributed over a larger surface area. Thus, it is respectfully submitted that claim 43 recites additionally allowable subject matter.

Newly presented claim 44 depends from claim 43 and thus, for at least the above reasons, is allowable. In addition, claim 44 recites that the at least one rod deflects radially outwardly in response to contacting of the corresponding intermediate segment with the bodily structure. Support for this language is found, for example, at page 12, line 32 – page 13, line 10; and in FIGS. 15A and 19B. The use of the longitudinally rigid expandable member 22 required by

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Saltiel is in direct opposition as Saltiel requires an unchanging distance between the distal end 24 and the manifold 14. Thus, it is respectfully submitted that claim 44 recites additionally allowable subject matter.

Newly presented claim 45 depends from claim 44 and thus, for at least the above reasons, is allowable. In addition, claim 45 recites that following initial contact of the at least one rod with the bodily structure, continued movement of the base toward the ostium causes the corresponding free end of the rod to displace radially outwardly. Support for this language is found, for example, at page 12, line 32 – page 13, line 10; and in FIGS. 15A and 19B. In contrast, use of the longitudinally rigid member 22 of Saltiel dictates that no radial displacement occurs following contact with the ostium structure. Thus, it is respectfully submitted that claim 45 recites additionally allowable subject matter.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 28-45 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 28-45 are respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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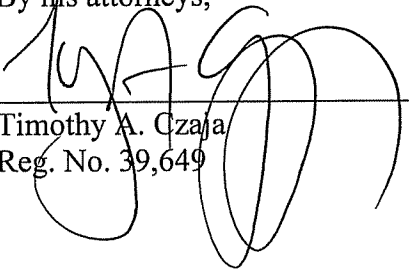
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Respectfully submitted,

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By his attorneys,

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